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MAIL STOP - PCT
Attorney Docket No.: 27391U

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of: Art Unit: Unknown
BRUECK-SCHEFFLER, Antje Examiner: Unknown
Application No.: 10/582,499
Filed: June 9, 2006
Intl. Application No.: PCT/EP2004/053495
Intl. Filing Date: December 15, 2004
Title: **AQUEOUS SUSPENSIONS OF CICLSONIDE FOR NEBULISATION**

TRANSMITTAL LETTER

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

Submitted herewith for filing in the U.S. Patent and Trademark Office is the following:

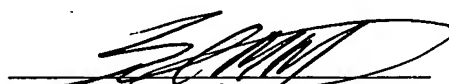
- 1) Information Disclosure Statement;
- 2) PTO Form-1449 with 53 cited references, and copies of 33 of the 53 cited references.

The Commissioner is hereby authorized to charge any deficiency or credit any excess to Deposit Account No. 14-0112.

Respectfully submitted,
NATH & ASSOCIATES PLLC

September 11, 2006

By:


Gary M. Nath, Reg. No. 26,965
Sheldon M. McGee, Reg. No. 50,454
Customer No. 34375

1e



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INFORMATION DISCLOSURE STATEMENT

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

An Information Disclosure Statement is submitted herewith pursuant to 37 C.F.R. 1.97-1.98. Please note the following particulars: [NOTE: One only of items a, b, c, and d must be checked.]

- a. ☒ [XXX] The enclosed statement is being filed within three months of the filing date of a national application, or within three months of the date of entry into the national stage as set forth in 37 C.F.R. 1.491 in an international application, or before the mailing date of a first Office Action on the merits, whichever event occurs last.
- b. ☐ [] The enclosed statement is being filed after a first action on the merits but before the mailing date of a final action under 37 C.F.R. 1.113, or a notice of allowance under 37 C.F.R. 1.311.
The enclosed statement is accompanied by [check one]:
☐ [] i. a certification in part (e) below as specified in 37 C.F.R. 1.97(e), or
☐ [] ii. a check in the amount required by 37 C.F.R. 1.17(p).
- c. ☐ [] The enclosed statement is being filed after the mailing date of a final action under 37 C.F.R. 1.113,

or a notice of allowance under 37 C.F.R. 1.311, but before payment of the issue fee.

☐ Certification report(e) below; and

☐ a check in the amount as required by 1.17(p).

d. ☐ The enclosed statement is being filed pursuant to 37 C.F.R. 1.97(i), for placement in the file.

e. Certification [Check one] [Certification is required only if box (b)(i) or box (c) is checked.]

☐ I hereby certify that each item of information contained in the enclosed Information Disclosure Statement was cited in a communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of this statement,

or

☐ I hereby certify that no item of information in the enclosed Information Disclosure Statement herewith was cited in a communication from a foreign patent office in a counterpart foreign application, or, to my knowledge after making reasonable inquiry, was known to any individual designated in 37 C.F.R. 1.56(c) more than three months prior to the filing of this Information Disclosure Statement.

or

☐ Appropriate certification is attached.

f. [XXX] If no check is enclosed and a fee is due in connection with this communication or if the check enclosed is insufficient, the Commissioner is authorized to charge any fee or additional fee due in connection with this communication to Deposit Account No. 14-0112.

g. [XXX] Copies of the documents are attached herewith with a completed PTO Form-1449.

[] or
Copies of the documents are not attached, with a completed PTO Form-1449 as allowed under CFR 1.98(d)(1)(2). The earlier application is identified as:

[XXX] and / or
Copies of US Patents/Publications not attached, with a completed PTO Form-1449 as allowed in Official Gazette Aug. 5, 2003/ Vol. 1273, no. 1.


The Examiner is respectfully requested to cite the documents listed on the attached Form PTO-1449 in the next Office Action. In so doing, the Examiner is respectfully requested to initial in the space adjacent to the listing of each document on the Form PTO-1449, and return a copy of the initialed Form PTO-1449 with the next communication to Applicants, to confirm that these documents have been considered by the Examiner and made of record in this application.

If the Examiner has any questions or wishes to discuss this application, kindly telephone the undersigned at the below-listed number.

Respectfully submitted,
NATH & ASSOCIATES PLLC

September 11, 2006

By:


Gary M. Nath, Reg. No. 26,965
Sheldon M. McGee, Reg. No. 50,454
Customer No. 34375

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FORM PTO-1449
INFORMATION DISCLOSURE
CITATION

In re Application of:
BRUECK-SCHEFFLER, Antje

Application No:
10/582,499

Art Unit:
Unknown

Filed: June 9, 2006

Examiner: Unknown

U.S. PATENT DOCUMENTS

Examiner Initial		Document Number	Issue / Publication Date	Inventor	Filed
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	A2	2003/0103864	6/5/2003	McAffer et al.	9/30/2002
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Examiner

Date Considered

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A50	Illum, L., et al., "Surface area stability of micronized steroids sterilized by irradiation", <u>Arch. Pharm. Chemi Sci. Ed.</u> , Vol. 2, p. 167-174, (1974).
A51	European Pharmacopoeia, Vol. 5.0, Chapter 5.1.1. on Methods of Preparation of Sterile Products, p. 445-447, (2005).
A52	US Pharmacopoeia, Vol. 26, Chapter 1211 on Sterilization and Sterility Assurance of Compendial Articles", p. 2433-2439.

Examiner

Date Considered

EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP ' 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to Applicant.

FORM PTO-1449 <u>INFORMATION DISCLOSURE</u> <u>CITATION</u>		In re Application of: BRUECK-SCHEFFLER, Antje	
		Application No: 10/582,499	Application No: 10/582,499
		Filed: June 9, 2006	Filed: June 9, 2006
OTHER			
Examiner Initial		(Including Author, Title, Date, Pertinent Pages, etc.)	
	A53	US Pharmacopoeia, Vol. 26, Chapter 71 on Sterility Tests", p. 2011-2016.	
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Examiner		Date Considered	
<small>EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP ' 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to Applicant.</small>			